K052738

DEC 6 2005

510(k) Summary

General Information

Classification	Class II
Trade Name	InfusionCath™ Peripheral Infusion Catheter
Submitter	VeinRx Inc 8200 N.W. 27th Street Suite 102 Miami, FL 33122 305-716-7005
Contact	Gregory J. Mathison Vice President – Regulatory Affairs

Intended Use

The VeinRx Infusion Catheter is intended for the infusion of physician specified fluids, including thrombolytics, into the peripheral vasculature.

Predicate Devices

InfusionCath Peripheral Infusion Catheter Manufactured by VeinRx, Inc.	K041517

Device Description

The VeinRx InfusionCath Peripheral Infusion Catheter is comprised of a distal occlusion balloon, a fixed infusion length catheter body with infusion holes, and a proximal trifurcated Luer connection hub. The trifurcated hub allows connection to three main systems of the device. The distal black marker indicates the proximal edge of the infusion length. The proximal black marker is used to properly align the device with the recommended introducer. The InfusionCath is packaged inside a protective tube mounted on a card and placed in a sealed protective pouch.

Materials

All materials used in the manufacture of the InfusionCath Peripheral Infusion Catheter are suitable for this use and have been used in numerous previously cleared products.

Testing Summary

The modified InfusionCath Peripheral Infusion Catheter was tested in the same manner as the original InfusionCath Peripheral Infusion Catheter. All components, subassemblies, and/or full devices met the required specifications for the completed tests.

Summary of Substantial Equivalence

The modified InfusionCath Peripheral Infusion Catheter is equivalent to the predicate product, the original InfusionCath Peripheral Infusion Catheter. The indications for use, function, methods of manufacturing, and materials used are substantially equivalent. VeinRx, Inc. believes the modified InfusionCath Peripheral Infusion Catheter is substantially equivalent to existing legally marketed devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 6 2005

Mr. Gregory Mathison
Vice President
Vein RX, Inc.
8299 NW 27 St.
Suite 102
Miami, FL 33122

Re: K052738
Trade Name: Infusion Catl™
Regulation Number: 21 CFR 870.3470
Regulation Name: Infusion Catheter
Regulatory Class: II (two)
Product Code: KRA
Dated: November 08, 2005
Received: November 11, 2005

Dear Mr. Mathison:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052738

Device Name: InfusionCath Peripheral Infusion Catheter

Indications For Use: The InfusionCath Peripheral Infusion Catheter is intended for infusion of physician specified fluids, including thrombolytics, into the peripheral vasculature

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vo Jones

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K052738